

Substitute for form 1449A/PTO				<i>Complete if Known</i>	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	10/541,195
				Filing Date	June 30, 2005
				First Named Inventor	Patricia SALVATI
				Group Art Unit	1617
				Examiner Name	Sahar JAVANMARD
				Confirmation No.	7746
Sheet	1	of	7	Attorney Docket No.	373987-004US (396982)

U.S. PUBLISHED DOCUMENTS					
Examiner Initials*	Cite No. ¹	U.S. Publication Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
A1	US-3,549,690			Leigh et al.	12-22-1970
A2	US-3,576,864			Nagarajan	04-27-1971
A3	US-3,658,967			Leigh et al.	04-25-1972
A4	US-4,049,663			Harper et al.	09-20-1977
A5	US-4,267,354			Krapcho et al.	05-12-1981
A6	US-4,311,853			Cree et al.	01-19-1982
A7	US-4,513,009			Roques et al.	04-23-1985
A8	US-4,631,287			Chakraborty et al.	12-23-1986
A9	US-4,639,468			Ronuccci et al.	01-27-1987
A10	US-4,725,608			Nakaguchi et al.	02-16-1988
A11	US-4,725,619			Chakraborty et al.	02-16-1988
A12	US-4,839,369			Youssefeyh et al.	06-13-1989
A13	US-4,927,835			Kise et al.	05-22-1990
A14	US-4,927,836			Holloway et al.	05-22-1990
A15	US-5,236,957			Dostert et al.	08-17-1993
A16	US-5,391,577			Dostert et al.	02-21-1995
A17	US-5,446,066			Varasi et al.	08-29-1995
A18	US-5,449,692			Varasi et al.	09-12-1995
A19	US-5,475,007			Cai et al.	12-12-1995
A20	US-5,482,964			Hays	01-09-1996
A21	US-5,498,610			Chenard	03-12-1996
A22	US-5,502,079			Dostert et al.	03-16-1996

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A23	US-5,670,546		Park et al.	09-23-1997
A24	US-5,688,830		Berger et al.	11-18-1997
A25	US-5,723,489		Sher et al.	03-03-1998
A26	US-5,741,818		Dimmock	04-21-1998
A27	US-5,849,737		Chaplan et al.	12-15-1998
A28	US-5,945,454		Peverello et al.	08-31-1999
A29	US-6,281,211		Cai et al.	08-28-2001
A30	US-6,303,819		Peverello et al.	10-16-2001
A31	US-6,479,484		Lan et al.	11-12-2002
A32	US-6,500,825		Lan et al.	12-31-2002
A33	US-7,091,210		Lan et al.	08-15-2006
A34	US-RE40,259		Peverello et al.	04-22-2008
A35	US-2004/0248978		Salvati	12-09-2004
A36	US-2007/0093495		Ruggero et al.	04-26-2007
A37	US-2007/0203182		Bessana et al.	08-30-2007
A38	US-2008/096965		Barbanhi et al.	04-28-2008

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Date of Publication of Cited Document MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Translation ²	
		Office	Number	Kind Code (if known)			Yes	No
	B1	EP	0200101	A2	12-10-1996	USV Pharmaceutical Corp.		
	B2	EP	0415143	A1	03-06-1991	Warner-Lambert Co.		
	B3	EP	0 525 360	A2	02-03-1993	Korea Research Institute of Chemical Technology		
	B4	GB	1140748		01-22-1969	Imperial Chemical Industries, Ltd		

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B5	GB	2059963	A	04-29-1981	A.H. Robins Co., Inc.	
B6	WO	90/14334		11-29-1990	Farmitalia Carlo Erba S.R.L.	
B7	WO	94/22808		10-13-1994	Pharmacia/Farmitalia Carlo Erba SRL	
B8	WO	94/22809		10-13-1994	Pharmacia/Farmitalia Carlo Erba	
B9	WO	96/40628		12-19-1996	The University of Saskatchewan	
B10	WO	97/05102		02-13-1997	Pharmacia & Upjohn S.p.A.	
B11	WO	97/05111		02-13-1997	Pharmacia & Upjohn S.p.A.	
B12	WO	98/19998		05-14-1998	Novartis AG	
B13	WO	98/25594		06-19-1998	SmithKline Beecham PLC	
B14	WO	98/43964		10-08-1998	Pharmacia & Upjohn S.p.A.	
B15	WO	98/47869		10-29-1998	CoCensys, Inc.	
B16	WO	99/26614		06-03-1999	CoCensys, Inc.	
B17	WO	99/35123		07-15-1999	Newron Pharmaceuticals SpA	
B18	WO	99/35125		07-15-1999	Newron Pharmaceuticals SpA	
B19	WO	99/39712		08-12-1999	CoCensys, Inc.	
B20	WO	00/61188		10-19-2000	CoCensys, Inc.	

OTHER DOCUMENTS - NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation ²		
			<input type="checkbox"/> Yes	<input type="checkbox"/> No	
C1		Anonymous, "Cambridge NeuroScience's grant for channel blockers," <i>SCRIP World Pharmaceutical News</i> 1870:8 (1993)			
C2		Anonymous, "Neurotonic Licenses National Institutes of Health (NIH) anticonvulsants," <i>SCRIP World Pharmaceutical News</i> 1773:14 (1992)			
C3		AWOUTERS (ed.), <i>Proceedings, XIVth International Symposium on Medicinal Chemistry</i> , Maastricht, The Netherlands, 8 - 12 September 1996, Elsevier Science B.V. (Amsterdam), (cover, front matter, table of contents, index of authors, subject index, Stanford University Libraries date stamp). Copyright 1997; date stamped 24 August 1998, Swain Library, Stanford University.			
C4		Bensimon, G., et al., "A Controlled Trial of Riluzole in Amyotrophic Lateral Sclerosis," <i>New Engl. J. Med.</i> 330:585-591 (1994)			

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C5	Brown, C.M., <i>et al.</i> , "Neuroprotective properties of Lifarizine compared with those of other agents in a mouse model of focal cerebral ischaemia," <i>British J. Pharmacol.</i> 115:1425-1432 (1995)		
C6	Catterall, W.A., "Common modes of drug action on Na ⁺ channels: Local anesthetics, antiarrhythmics and anticonvulsants," <i>Trends Pharmacol. Sci.</i> 8:57-65 (1987)		
C7	Catterall, W.A., "Neurotoxins that Act on Voltage-Sensitive Sodium Channels in Excitable Membranes," <i>Ann. Rev. Pharmacol. Toxicol.</i> 20:15-43 (1980)		
C8	Catterall, W.A., "Structure and Function of Voltage-Sensitive Ion Channels," <i>Science</i> 242:50-61 (1988)		
C9	Complaint, Civil Action No. 1:07-cv-00487 (March 12, 2007)		
C10	Denicoff, K.D., <i>et al.</i> , "Efficacy of Carbamazepine Compared With Other Agents: A Clinical Practice Survey," <i>J. Clin. Psychiatry</i> 55:70-76 (1994)		
C11	Decision, Preliminary Motions, Bd.R. 125, interference no. 105,394 (2007)		
C12	Dimmock, J.R., <i>et al.</i> , "(Aryloxy)aryl Semicarbazones and Related Compounds: A Novel Class of Anticonvulsant Agents Possessing High Activity in the Maximal Electroseshock Screen," <i>J. Med. Chem.</i> 39:3984-3997 (1996)		
C13	Dostert <i>et al.</i> , "New anticonvulsants with selective MAO-B inhibitory activity," <i>European Neuropsychopharmacology</i> , 1(3):317-319 (September 1991)		
C14	ELRIFI <i>et al.</i> , "Request for <i>ex parte</i> reexamination of U.S. patent no. 6,479,484 B1," filed July 2, 2003 on behalf of Newron Pharmaceuticals, SpA		
C15	FARIELLO <i>et al.</i> , "Preclinical evaluation of PNU-151774E as a novel anticonvulsant," <i>J. Pharmacol. Exp. Ther.</i> 285(2):397-403 (May 1998)		
C16	Faravelli L. <i>et al.</i> , "NW 1029 is a novel na ⁺ channel blocker, with analgesic activity in animal models." Abstract, Annual Meeting, Society for Neuroscience 2000; 26 (1):1218		
C17	Fields, "Peripheral neuropathic pain: an approach to management," <i>In</i> PD Wall and R Melack (eds.), <i>Textbook of Pain</i> , 3 rd ed., Churchill Livingstone, pp. 991-996 (1994)		
C18	(First) Declaration of Robert A. McArthur, Pevarello Exhibit 2036, interference 105,394 (2006)		
C19	First Declaration of Stephen G. Waxman, M.D., Ph.D., PX 2003, interference no. 105,394 (2006)		
C20	Galer BS, "Neuropathic pain of peripheral origin: advances in pharmacologic treatment," <i>Neurol.</i> 45:S17-S25, 1995		
C21	Guieu <i>et al.</i> , "Central analgesic effect of valproate in patients with epilepsy," <i>Seizure</i> 2:147-150 (1993)		

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C22	Graham, S.H., <i>et al.</i> , "Neuroprotective Effects of a Use-Dependent Blocker of Voltage-Dependent Sodium Channels, BW619C89, in Rat Middle Cerebral Artery Occlusion," <i>J. Pharmacol. Exp. Ther.</i> 269:854-859 (1994)		
C23	Hammer <i>et al.</i> , "Effect of Ribuzole on acute pain and hyperalgesia in humans," <i>Brit. J. Anaesthesia</i> 82(5):718-22 (1999)		
C24	International Search Report for PCT/EP03/12889 dated Feb. 3, 2004.		
C25	Judgment, Preliminary Motions, Bd.R. 127, interference no. 105,394 (2007)		
C26	Kingery, "A critical review of controlled clinical trials for peripheral neuropathic pain and complex regional pain syndromes," <i>Pain</i> 73:123-139 (1997)		
C27	Lunardi <i>et al.</i> , "Clinical effectiveness of lamotrigine and plasma levels in essential and symptomatic trigeminal neuralgia," <i>Neurology</i> 48(6):1714-1717 (1997)		
C28	Magnus L., "Nonepileptic uses of gabapentin experience, <i>Epilepsia</i> , 1999; 40 (Suppl. 6) S66-72; discussion 873-874		
C29	Mathew, Ninan T., "Pathophysiology, epidemiology and impact of Migraine" <i>Clinical Cornerstone</i> , vol. 4, no. 3, 2001, pages 1-17		
C30	May <i>et al.</i> , "The trigeminovascular system in humans: pathophysiologic implications for primary headache syndromes of the neural influences on the cerebral circulation," <i>J. Cereb. Blood flow Metab.</i> , vol. 9, 1999, pages 115-127		
C31	McQuay <i>et al.</i> , "Anticonvulsant drugs for management of pain: a systematic review," <i>BMJ</i> 311:1047-1052 (21 October 1995)		
C32	Memorandum Opinion and Order, interference no. 105,394 (2007)		
C33	Nakamura-Craig <i>et al.</i> , "Effect of lamotrigine in the acute and chronic hyperalgesia induced by PGE ₂ and in the chronic hyperalgesia in rats with streptozocin-induced diabetes," <i>Pain</i> 63:33-37 (1995)		
C34	Notice Of Dismissal With Prejudice, Civil Action No. 1:07-cv-00487 (July 25, 2007)		
C35	Official action, counterpart Brazilian application (to RE40,259) no. PI 9814548-7 (translation) (AUGUST 14, 2007)		
C36	Peiti B. <i>et al.</i> , "Capsaicin-insensitive sensory-fferent meningeal vasodilatation evoked by electrical stimulation of trigeminal nerve fibres in the rat," <i>British Journal of Pharmacology</i> (1999) 127, 457-467.		
C37	Pesarello <i>et al.</i> , "Synthesis and Anticonvulsant Activity of a New Class of 2-[(Arylalkyl)amino]alkanide Derivatives", <i>J. Med. Chem.</i> 41:579-590 (1998)		
C38	PEVARELLO <i>et al.</i> , "Stereoselectivity, sigma binding and sodium channel blocking activity of 2-amino propanamide anticonvulsants." (3 pages) (September 12, 1996).		
C39	Puig <i>et al.</i> , "Formalin-evoked activity in identified primary afferent fibers: systemic lidocaine suppresses phase-2 activity," <i>Pain</i> 64:345-355 (1995)		

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C40	Reuter U. <i>et al.</i> , "Experimental models of migraine", <i>Functional neurology</i> (15) Suppl. 3 9-18, 2000		
C41	SALVATI <i>et al.</i> , "Anticonvulsant profile of FCE26743A (PNU-151774), a novel 2-aminopropionamide derivative. Society for Neuroscience. Washington. Nov 15 - 21, 1996." (4 pages) (November 21, 1996, date solely for purpose of initial consideration)		
C42	Saxena <i>et al.</i> , "Pharmacology of antimigraine drugs," <i>Journal of Neurology</i> , 1991, pages S28-S35		
C43	Shibata <i>et al.</i> , "Modified formalin test: characteristic biphasic pain response," <i>Pain</i> 38:347-352 (1989)		
C44	Steiner <i>et al.</i> : "Lamotrigine versus placebo in the prophylaxis of migraine with and without aura" <i>Cephalgia</i> , vol. 17, 1997, pages 109-112		
C45	Stys, P.K., <i>et al.</i> , "Ionic Mechanism of Anoxic Injury in Mammalian CNS White Matter: Role of Na ⁺ Channels and Na ⁺ -Ca ²⁺ Exchanger," <i>J. Neurosci.</i> 12:430-439 (1992)		
C46	Supplemental data, Vieth <i>et al.</i> , "Characteristic Physical Properties and Structural Fragments of Marketed Oral Drugs," <i>J. Med. Chem.</i> 47:224-232 (2004) (downloaded August 20, 2007 from http://pubs.acs.org) (excerpted fields)		
C47	Tanelian <i>et al.</i> , "Neuropathic pain can be relieved by drugs that are use-dependent sodium channel blockers: lidocaine, carbamazepine, and mexiletine," <i>Anesthesiol.</i> 74(5):949-951 (1991)		
C48	Tanelian <i>et al.</i> , "Sodium channel-blocking agents: their use in neuropathic pain conditions," <i>Pain Forum</i> 4(2):75-80 (1993)		
C49	Taylor, C.P. and Meldrum, B.S., "Na ⁺ channels as targets for neuroprotective drugs," <i>Trends Pharmacol. Sci.</i> 16:309-316 (1995)		
C50	Tjolsen <i>et al.</i> , "The formalin test: an evaluation of the method," <i>Pain</i> 51:5-17 (1992)		
C51	Vaghi <i>et al.</i> , "Neuroprotective effect of PNU-151774E, a new anticonvulsant compound, in the model of global ischaemia in gerbils." (5 pages) (October 30, 1997, date solely for purpose of initial consideration)		
C52	Varasi <i>et al.</i> , "Synthesis and anticonvulsant activity of new benzyl oxybenzylacetamide derivatives," from <i>Abstracts, XIIth International Symposium on Medicinal Chemistry</i> , Basel, Switzerland, September 13-17, 1992 (2 pages) (1992)		
C53	Varasi <i>et al.</i> , "Synthesis and anticonvulsant activity of new benzyl oxybenzylacetamide derivatives" (2 pages) (1992)		
C54	Vieth <i>et al.</i> , "Characteristic Physical Properties and Structural Fragments of Marketed Oral Drugs," <i>J. Med. Chem.</i> 47:224-232 (2004)		
C55	Webber, "Observations under article 115 EPC", filed November 19, 2002 in EP 98958114.5 (EP 1032377) on behalf of Newron Pharmaceuticals, SpA		

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	C56	Wenzel <i>et al.</i> : "Migraine headache misconceptions: barriers to effective care" <i>Pharmacotherapy</i> , vol. 24, no. 5, 2004, pages 638-648		
	C57	Wilton, "Tegretol in the treatment of diabetic neuropathy," <i>S. Afr. Med. J.</i> 48(20):869-872 (1974)		
	C58	Woolf <i>et al.</i> , "The systemic administration of local anaesthetics produces a selective depression of C-fferent fibre evoked activity in the spinal cord," <i>Pain</i> 23(4):361-374 (1985)		

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